Statement of

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"Prescription Drug Abuse: What is Being Done to Address This New Drug Epidemic?"

Chairman Souder, Ranking Member Cummings, and distinguished members of Subcommittee, on behalf of Administrator Tandy and the Drug Enforcement Administration (DEA), I appreciate your invitation to testify today regarding DEA's efforts to address the issue of prescription drug abuse.

Overview

Addressing the growing problem of the diversion and abuse of controlled pharmaceuticals continues to be one of the top priorities of the Drug Enforcement Administration. DEA has made great strides in dealing with this ever-changing, global drug issue. We continue to concentrate on identifying, targeting, and dismantling large-scale organizations that seek to divert and distribute controlled pharmaceuticals in violation of the Controlled Substances Act (CSA). An illustration of the Administration's focus on this problem occurred on June 1, 2006, when the Department of Justice, along with the DEA, the Office of National Drug Control Policy, the Department of Homeland Security, the Department of Health and Human Services, and other agencies announced a comprehensive Synthetic Drug Control Strategy, which among other significant drug threats, specifically targets prescription drug abuse. The DEA is keenly aware of this problem.

An examination of youth drug abuse data reveals that the percentage of young Americans abusing prescription drugs is second only to marijuana and ahead of cocaine, heroin, methamphetamine, and other drugs. DEA, as the nation's primary law enforcement agency dedicated to enforcing the Controlled Substances Act, plays an integral role in achieving the goals of the Administration's Synthetic Drug Control

Strategy. As outlined in that Strategy, we have committed to an ambitious goal of reducing the abuse of controlled pharmaceuticals by 15 percent over the next three years.

DEA's obligation under the law and to the public is to ensure that pharmaceutical controlled substances are prescribed and dispensed only for legitimate medical purposes in accordance with the Controlled Substances Act. By carrying out this obligation, DEA strives to minimize the diversion of pharmaceutical controlled substances for abuse while ensuring that such medications are fully available to patients in accordance with the sound medical judgments of their physicians. In this manner, DEA is committed to balancing the need for prevention, education, and enforcement with the need for legitimate access to these drugs.

In developing a strategy to balance these priorities, the Administration has worked to obtain better data on how people acquire and abuse controlled pharmaceuticals. It is important to understand that there are distinct differences between drugs such as heroin or marijuana and controlled pharmaceuticals. As we know, illegal drugs such as cocaine, heroin, and marijuana often are obtained through secretive and dangerous transactions. Typical drug control strategies used to attack organizations that focus on distribution of clandestine drugs do not necessarily lend themselves to attacking those organizations that illegally traffic in controlled pharmaceuticals.

Controlled pharmaceuticals are readily available for legitimate purposes through one's physician and pharmacy. Distribution channels that are otherwise legal are often manipulated to acquire controlled substance prescription drugs for illegal purposes. Compounding this matter is the perception, particularly among teenagers and young adults that controlled pharmaceuticals are safe even when used "recreationally." Abusers of controlled pharmaceuticals are using these medicines for non-medical purposes in a manner for which they were never intended. This practice, coupled with the erroneous perception of safety, makes these medicines much more dangerous.

DEA Initiatives

DEA has not remained idle in response to this growing threat. DEA has made it a priority to disrupt and dismantle organizations that illegally traffic in controlled pharmaceuticals. This priority is reflected in the fact that diversion control is a strategic goal in the DEA five-year Strategic Plan. Part of this strategy is to attack the economic basis of the drug trade by inflicting upon the illicit drug business what every legal business fears: escalating costs, diminishing profits, and unreliable suppliers. To do so, DEA uses all of the tools at its disposal. We have dismantled major pharmaceutical trafficking and distribution organizations through criminal investigations. We have also used our regulatory authority to take action against DEA registrants found to be in violation of regulatory requirements under the CSA. Through regulatory authority, DEA has subjected registrants to significant civil fines, licensing restrictions, or even suspended registrations. Such civil remedies have proven to be an effective deterrent to potential violators.

As we have observed the pharmaceutical controlled substances abuse problem grow, DEA has significantly increased the amount of resources and manpower dedicated to investigating the diversion of controlled pharmaceuticals. We continue to focus our drug enforcement efforts on the most significant diverters in the drug supply chain. Specifically, DEA has increased the number of Special Agent work-hours on diversion investigations by 114 percent between FY-2003 and FY-2005. DEA has increased the number of Intelligence Analyst work-hours by 234 percent during that same period. Enforcement efforts undertaken by the DEA are also aimed at the economic base of drug traffickers, and strong emphasis is placed on seizures of financial and other assets. In FY-2002 DEA seized approximately $1.8 million in assets related to diversion investigations. In FY-2005 that increased to approximately $32.4 million, an 1,800 percent increase.

In early FY 2005, the DEA began working with its industry partners to develop public service announcements that now appear automatically during Internet prescription drug searches. These announcements are designed to alert consumers of the potential dangers and the illegality of purchasing controlled substances, particularly pharmaceuticals, over the Internet. Both Yahoo and Google have responded by instituting voluntary compliance measures and corporate commitments to taking affirmative steps to curtail the illicit sale of pharmaceuticals on their networks.

In addition, DEA's Demand Reduction office has produced an anti-drug website for teens, www.justthinktwice.com. This site provides young people with straightforward information on the consequences of drug use and trafficking, including health, social, legal consequences. It is continually updated to provide current information to teens and will be expanded and refined to reflect the needs of teens. This site has been a valuable (and popular) resource for teens seeking information on drugs for their own education or for school research projects. The Demand Reduction Program also continues to provide the public and school age children with a variety of demand reduction presentations on a national and local level regarding the abuse of controlled prescriptions.

Finally, the DEA has met with the leading certifying medical boards and encouraged them to develop educational programs concerning the prescribing of controlled substances, especially high-dose opioids.

Sources of Abused Pharmaceuticals

Pharmaceutical investigations and surveys of state and local law enforcement agencies and state medical boards have revealed that the most common methods of controlled substance prescription drug diversion include "doctor shopping" or other prescription fraud, illegal online pharmacies, theft and burglary (from residences, pharmacies, etc.), stereotypical drug dealing (selling pills to others), receiving from friends or family, and negligent or intentional over-prescribing by physicians or other practitioners. What is not yet adequately understood is the relative proportion of these methods.

Doctor Shopping and Prescription Fraud

"Doctor shopping" by drug addicts is one of the most common ways that addicts get illegal controlled substances. Generally, this term refers to the visit by an individual—who may or may not have legitimate medical needs—to several doctors, each of whom writes a prescription for a controlled substance. The individual will visit several pharmacies, receiving more of the drug than intended by any single physician, typically for the purpose of feeding an addiction.

Associated illegal activities may include the forgery of prescriptions, or the sale or transfer of the drug to others. Unfortunately, in many states, physicians and pharmacists have not been able to automatically cross-check multiple prescriptions given to the same patient.

To address this problem, Congress first appropriated funds to the Department of Justice in 2003 to promote the deployment of Prescription Drug Monitoring Programs (PDMPs) by States. That commitment continues as part of the Administration's National Drug Control Strategy for 2006. PDMPs help cut down on prescription fraud and doctor shopping by giving physicians and pharmacists more complete information about a patient's prescriptions for controlled substances.

While the specifics of these programs vary from state to state, they generally share the characteristic of allowing prescribers (for example, a physician) and dispensers (for example, a pharmacist) to input and receive accurate and timely controlled substance prescription history information while ensuring patient access to needed treatment. Most states also have some mechanism for law enforcement to receive this information in cases where criminal activity is suspected. Some states also allow health care providers to use this information as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions. In other states the justice system can use this information to assist in the enforcement of laws controlling the sale and use of controlled substance prescription medication.

The PDMP program has steadily expanded through the Harold Rogers Prescription Drug Monitoring Program, with a total of 33 states with active or planned PDMPs as of July 1, 2006. These grants can be used to implement or enhance PDMPs at the state level. The Administration plans to continue its work with states that have PDMPs to obtain better data as to the extent and nature of the controlled substance prescription drug abuse threat, to encourage the expansion of the PDMP program nationwide, and to share best practices information with states that already have PDMPs (e.g., on cost effectiveness, the benefits to monitoring all scheduled controlled substances, and measuring performance).

Improper Prescribing

Improper prescribing is another method of controlled substance diversion. Improper prescribing differs from doctor shopping and prescription fraud in that the latter situations, the abusers are attempting to deceive or mislead the medical professionals who are doing their jobs responsibly.

The overwhelming majority of prescribing in America is conducted responsibly. Often these responsible doctors and pharmacists are the first to alert law enforcement to potential prescription problems. However, the small number of physicians who over prescribe controlled substances—carelessly at best, knowingly at worst—help supply America's second most widespread drug addiction problem. Although the problem exists, the number of physicians and pharmacists responsible for this problem is a very small fraction (less than 1 percent) of those licensed to prescribe and dispense controlled substances in the United States.

Sharing Among Family and Friends

As DEA increases its understanding of where abusers acquire prescription drugs, preliminary data suggest that the most common method in which controlled substance prescriptions are diverted may be through friends and family. For example, a person with a lawful and genuine medical need for a controlled substance may use only a portion of the prescribed amount. A family member or friend may complain of similar symptoms, and the former patient shares excess medication. Alternatively, for someone addicted to controlled substance prescription drugs or to an inquisitive youngster, the mere availability of unused controlled substance prescriptions in the house may prove to be an irresistible temptation.

The solution to this aspect of the problem lies both with the medical community and the legitimate patient population. Greater educational efforts are needed regarding quick and safe disposal of unused and unneeded medications. Prescribers need to carefully consider the potential for abuse of controlled substances and prescribe only the amount of a controlled substance required medically. Patients must also be educated about the legal and social ramifications of providing a controlled substance to a friend or family member. It is not merely illegal, but could feed, or lead to, an addiction, and place that loved one in a life threatening situation.

Illegal Online Pharmacies

Perhaps the most potentially dangerous and increasingly used method for the diversion of controlled pharmaceuticals is through the Internet. As the number of Americans with Internet access has increased, so too have opportunities for individuals to acquire controlled substance prescription drugs over the Internet. There are strong societal benefits to allowing individuals with a valid prescription to get their prescriptions over the Internet, as long as the pharmacy that fills these prescriptions is a legitimate one and there is a legitimate doctor-patient relationship. This may be helpful in rural areas or

for individuals who are homebound due to illness or other factors. However, the anonymity of the Internet, and the proliferation of websites that facilitate illicit transactions in controlled substance pharmaceutical drugs, have given drug abusers the ability to circumvent both the law and sound medical practice.

There are legitimate pharmacies that provide services over the Internet and that operate well within the bounds of both the law and sound medical practice. The National Association of Boards of Pharmacy has established a registry of pharmacies that operate online and meet certain criteria, including compliance with licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals.

By contrast, other websites used by Internet facilitators will often advertise themselves as pharmacies, but they do not operate in the same manner as brick-and-mortar pharmacies. Many of these websites advertise controlled substances without a prescription, and none include an in-person medical examination from a licensed physician.

Of particular concern is the cursory and abbreviated nature of the medical interaction. Often, if there is any interaction with a medical professional at all, the Internet facilitator will provide only a cursory doctor consultation by computer or telephone for customers. This brief interaction is not meant to elicit meaningful health information, and is generally done by way of a "questionnaire" filled out by the "patient" without any face-to-face meeting between the doctor and the patient. Without this face-to-face interaction, it is not possible for the doctor writing the prescription, who has never met the patient, to verify the information provided by the individual and assess legitimate medical need. This is particularly troubling in the context of youth drug abuse. Unlike when the patient visits the doctor, a minor can easily log onto a website and provide an inaccurate age.

Doctors, who are often paid by the number of prescriptions they sign in these situations, have no incentive to spend time seeking additional patient information. Law enforcement has discovered website-affiliated doctors who sign hundreds or thousands of prescriptions a day. After receiving the prescription from the doctor, the facilitator will then submit the prescription to a cooperating pharmacy. Because there is often no identifying information on these rogue websites, it is very difficult for law enforcement to track any of the individuals behind them.

The Administration is using all available tools to go after the operators of these rogue Internet-facilitator websites. We are conducting investigations and working to intercept controlled substance prescriptions illegally sent into the United States through the mail system. For example, the DEA's Internet investigation unit at its Special Operations Division continues to coordinate Internet cases, and the DEA has issued a number of immediate suspensions of the DEA registrations of doctors and pharmacies operating illegally via the Internet. The Department of Justice has prosecuted doctors and pharmacies who illegally distribute via the Internet.

The tangible aspects of manufacturing, distributing, prescribing, and dispensing pharmaceutical controlled substances remain squarely under the jurisdiction of the CSA. Any legitimate transaction over the Internet must be in compliance with these existing laws.

Additional clarification of the roles and responsibilities for professionals seeking to use the Internet to meet the needs of clients would not only allow us to more readily identify legitimate online pharmacies and persons operating and promoting them, but it would also assist in gathering information pointing to abuse patterns. Such clarification would also help us investigate drug traffickers hiding behind the façade of an otherwise legitimate practice.

Additionally, there exists no statutory definition of a valid "doctor/patient" relationship. Finally, the penalties associated with the illegal sale of Schedule III-V substances, which are those most commonly sold controlled substances over the Internet, are not as significant as may be warranted.

States can play a significant role in addressing the problem of online facilitators, particularly through PDMPs. As part of the Administration's work with states regarding PDMPs over the next several years, states will be encouraged to consider addressing, either by statute, regulation, or interstate agreement, a number of scenarios that primarily involve pharmacies dispensing or delivering controlled substance prescription drugs to patients across state lines. To be effective, laws must be updated to reflect the changing ways people live and in which business is conducted.

Coordinating Regulatory Responsibilities

As the DEA fights against diversion and drug abuse across the nation, the proper regulatory control of new pharmaceuticals is vital. Appropriate control mechanisms are particularly important given the strength and formulations of products as they become available to the consumer. This is important to the DEA as we are seeing an overall increase in the commercial dispersion of pharmaceuticals which results in a significant increase of pharmaceutical doses available for diversion. Understanding the differences–and the similarities–between prescription drugs and controlled substances is an important aspect of evaluating the causes and possible policy solutions regarding the rise in prescription drug abuse.

Congress signaled its full recognition of the abuse potential of certain prescription drugs in 1914, when it passed the Harrison Narcotic Act, regulating the sale of opiates for the first time. With the passage of the Federal Food, Drug and Cosmetic Act (FDCA) in 1938 and in subsequent amendments, the United States Congress recognized the critical importance of indicating the medically proven uses of prescription drugs for legitimate medical needs.

The CSA is the legal foundation for the United States fight against abuse of drugs and other substances. It was passed to minimize the quantity of abuseable substances

available to those likely to abuse them, while providing for legitimate medical, scientific and industrial needs for those substances in the United States. Control under the CSA encompasses both licit and illicit substances and regulates chemicals used in the clandestine production of controlled substances. The Department of Justice (DOJ), through the DEA, and the Department of Health and Human Services (HHS), through the FDA, both have a role in implementing the CSA.

The CSA requires that substances be scheduled by a determination made by the Attorney General, after a scientific and medical evaluation and recommendation by the Secretary of HHS (See 21 USC 811(b)). Substances with a substantial potential for abuse are considered for control under Schedules II through V. Schedule II substances have the highest abuse potential and dependence profiles with the most restrictive regulatory requirements, while III through V drugs have progressively less abuse potential and dependence profiles and are subjected to less restrictive regulatory requirements.

The placement of a substance in a given schedule is based on its medical use, safety, potential for abuse, or dependence liability, and consideration of specific factors as listed in the CSA. For drug products containing substances that are not already controlled under the CSA, as in the case of new molecular entities, HHS will forward their scientific and medical evaluation and a scheduling recommendation to the DEA. FDA has the statutory responsibility to determine the safety and effectiveness of new drug products for medical use in the United Sates. As a part of their evaluation, FDA also examines the abuse potential of drug products.

The CSA includes seven major control mechanisms. They are scheduling, registration, quotas, records and reports, import and export authorizations, security and investigational authority. These mechanisms allow DEA to monitor and regulate a controlled substance and its movement: in the case of the most potentially dangerous drugs, in Schedule II, we register all persons who handle them; we inspect the documentation of their distribution; we control their import and export; and we control the amount produced, bought, sold, and otherwise transferred.

These controls have been extremely effective in preventing diversion at the importer, manufacturer, and distributor levels. However, as described earlier, the vast majority of diversion occurs at the retail level, once the product is in the hands of practitioners and patients.

Conclusion

The diversion of pharmaceutical controlled substances continues to be a significant challenge. Nevertheless, the DEA is committed to using the necessary tools at its disposal to fight this growing problem on all fronts, while simultaneously ensuring an uninterrupted supply of pharmaceutical controlled substances for legitimate demands. DEA's core competency, the disruption and dismantlement of drug trafficking organizations impacting the United States, is an integral component to the Synthetic Drug

Control Strategy and we will continue to implement this aspect of the Strategy with our inter-agency partners to combat controlled substance pharmaceutical diversion.

Chairman Souder, Ranking Member Cummings, and distinguished Members of the Subcommittee, thank you again for the opportunity to testify before you today. Prescription drug abuse is an increasing threat that we must face, and DEA looks forward to working with you to address this important issue. I'll be happy to answer any questions you may have.